510(k) Summary

[As described in 21 CFR 807.92]

JUL 0 3 2013

Submitted by:

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Trade Name: Welch Allyn CP150™ Electrocardiograph
901049 Electrocardiograph

Common Name: Electrocardiograph

Classification Reference: Class II, Electrocardiograph (21 CFR 870.2340, Product Code DPS)

Predicate Device: Welch Allyn CP100™ and CP200™ Electrocardiographs
510(k) Number: K072449
Electrocardiograph, 21 CFR 870.2340
Class II, DPS

Description of the Device:

The Welch Allyn CP150™ Electrocardiograph is an electrocardiograph used to process the electrical signal transmitted through two or more electrocardiograph electrodes and to produce a visual display of the electrical signal produced by the heart. Its features include a 7" color touch screen display for ECG preview and user-friendly interface, full-size user-programmable reports, and the ability to operate on either battery or AC power.

The CP150™ Electrocardiograph is able to connect either via USB cable or via wired ethernet (RJ45 connector) across the ethernet network, which in turn can connect with other electronic patient-information systems, such as billing and medical records. The USB port can also be used to connect other accessory devices.

The CP150™ Electrocardiograph is specifically intended for acquiring and printing ECG signals from adults and pediatric patients. It will be used in clinical settings by trained healthcare providers.

The optional interpretation algorithm analyzes these ECG signals to generate measurements and interpretive statements. The interpretive results are intended only as guidance for qualified physicians and must not be relied upon as diagnoses.

Indications for Use:

The electrocardiograph is one of the tools that clinicians use to evaluate, diagnose, and measure patient cardiac function.

The 12-lead optional interpretation algorithm provides a computer-generated analysis of potential patient cardiac abnormalities, which must be confirmed by a physician with other relevant clinical information.

Contraindications:

There are no known contraindications for use.

Technological Characteristics:

The subject device has the same technological characteristics and indications for use as the predicate; The hardware, software, and mechanical aspects of the CP150 have been updated to current technology equivalent to the cleared devices (CP100™ and CP200™ Electrocardiographs, K072449, S.E. dated Nov. 29, 2007) as described below. The modification is to replace the display, i.e. 5.7 inches color LCD display, with a 7" color touch screen display for ECG preview. The physical QWERTY keyboard and other hard function keys used on CP100/CP200™ will be replaced by the touch screen interface. Additionally included are minor software and connectivity enhancements to improve performance and customer experience.

Non-Clinical Tests:

The Welch Allyn CP150™ Electrocardiograph was tested to evaluate its safety and effectiveness based on the following standards:

Standard	Version	Title
EN/IEC 60601-1	2nd Edition 2000	Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
EN/IEC 60601-1-2	2007	Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests

EN/IEC 60601-1-4	2000	Medical Electrical Equipment – Part 1-4: General Requirements for Safety – Collateral Standard: General Requirements for Programmable Electrical Medical Systems
AAMI EC-11	1991 (R2007)	Diagnostic electrocardiographic devices
IEC/EN60601-2-25	1993 AMD 1 1999	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
IEC/EN60601-2-51	2003	Particular Requirements For Safety, Including Essential Performance, Of Recording And Analysing Single Channel And Multichannel Electrocardiographs
EN/ISO 14971	2007/2007	Medical Devices – Application of Risk Management to Medical Devices

Additional performance Bench Testing:

Report DIR --- Description	Objective of the Test	Test Method/ Procedure	Pass/Fail Criteria	Conclusions
60048998 --- CP150 Connectors Reliability	To verify the reliability of all connectors of CP150 as per CP150 Technical Requirements Specification (TRS) (DIR 60047341) and CP150 Reliability Plan (DIR 60046890) including: • AC power inlet • ECG (DB15) • Ethernet (RJ45) • mini USB (USB B) • USB	1. Insert connector into the inlet 2. Conduct an Interval Inspection after every 10 insert/remove cycles. 3: Repeat steps 1-2 for greater than the minimum number of cycles listed in Pass/Fail criteria	• AC power inlet; 50 connect/disconnect cycles. • ECG (DB15), 50 connect/disconnect cycles. • Ethernet (RJ45), 100 connect/disconnect cycles. • mini USB (USB B) 100 connect/disconnect cycles. • USB, 400 connect/disconnect cycles.	**PASS**: The connectors meet the requirements of TRS and reliability plan
60048999 --- CP150 Battery Capacity Test	To verify the battery capacity for number of standard use cycles available without re-charging the battery	1. Using only the battery (fully charged), perform 25x ECG print tests 2. ECG test duration should take 15 minutes 3. Check battery capacity after each ECG print test	The device shall have the capacity to complete 25 ECGs over a 12 hour period with a single fully charged battery. Each ECG test is assumed taken in 15 minutes cycle with two copies of ECG prints	**PASS**: The battery meets the requirements of TRS

60049000 --- CP150 Battery Door & Connector	To verify the reliability of Battery Door and Battery Connector for number of standard use (insert/remove) cycles	1. Unscrew the Battery Door. Remove the battery fully. Insert back the battery and close the battery door and screw back to secure. 2. Conduct an Interval Inspection after every 10 insert/remove cycles.	TRS 4.8 4.8:The battery connector shall have a useable life shall be at least 10 connect/disconnect cycles and the door needs to pass 230 cycles of opening/closing.	**PASS**: The battery door and battery connector meet the requirements of TRS
60049001 --- CP150 Power Button Test	To verify the reliability of Power Button by number of presses as per CP150 Reliability Plan (DIR 60046890) requirements	• Press the Power Button with a nominal force as to power up the unit. Hold for one second then release. • Conduct an Interval Inspection after every 2,500 presses.	Reliability Plan 8.5: The test should meet zero failures for a total of 48,909 presses on 1 unit	**PASS**: The Power Button meets the requirements of reliability plan

60049002 --- CP150 LCD Touchscreen Test	To verify the reliability of LCD Touchscreen by applying mechanical touches on the screen as per CP150 Reliability Plan (DIR 60046890) requirements	• Install the 'touch finger' with silicone rubber region above the LCD Touchscreen. Adjust the input force to be 350g. • Set the same for the other 5 'touch finger' • Setup test speed to 1 Hz and start the test. • Conduct an Interval Inspection after every 60,000 touches. • Shift the 'touch finger' to other positions	Reliability Plan 8.5: All the functional tests must pass for total of 1,687688 touches on 3 unites (please see the rational on analysis column on the right)	**PASS**: The test results shows the LCD touchscreen meets the requirements of Reliability plan

60049003 --- CP150 Environment Test	To verify the device shall operate at temperature between 10.oC and 40.oC and at a relative humidity of 15% to 95% (non condensing) For printing the humidity is limited to 30% to 70% (non-condensing)	Device dwells for at least 6 hours at each operating conditions After every 3 hours dwell at each condition, perform an intermediate verification test	All the intermediate verification test was passed for following conditions: Acquiring ECG with Printing • +5°C / 30% RH for 6 hours • +5°C / 70% RH for 6 hours • +45°C / 30% RH for 6 hours • +45°C / 30% RH for 6 hours Acquiring ECG without Printing • +5°C / 10% RH for 6 hours • +5°C / 95% RH for 6 hours • +45°C / 10% RH for 6 hours • +45°C / 95% RH for 6 hours	**PASS**: The test results shows the CP150 meets the environmental test requirements of Reliability plan
--- CP150 Barcode scanner verification	To verify that the device will have the ability to input barcode alphanumeric inputs via a bar code scanner	1. Connect barcode scanner to the device 2. Scan the sample Serial number and verify the result 3. Repeat step 2 for 58 times	Scanned results should match the sample serial number in the box	**PASS**: The test results shows the bar code scanner meets the requirements of Reliability plan

60052441 --- 60601-1 Safety test	Test the device per 60601-1 to ensure that the device meets the safety requirements for medical devices	Units delivered to independently certified test lab for testing per compliance with standard.	Devices pass criteria of 60601-1	**PASS** Devices are compliant with 60601-1 standard
60052442 --- 60601-1-2 Electromagnetic Compatibility test	Test the device per 60601-1-2 to ensure that the device meets the requirements for Electromagnetic Compatibility	Units delivered to independently certified test lab for testing per compliance with standard.	Devices pass criteria of 60601-1-2	**PASS** Devices are compliant with 60601-1-2 standard
60052441 - 60601-1-4 Medical Electrical Equipment – Part 1-4: General Requirements for Safety – Collateral Standard: General Requirements for Programmable Electrical Medical Systems	Test the device per 60601-1-4 to ensure that the device meets the requirements for Programmable Electrical Medical Systems	Units delivered to independently certified test lab for testing per compliance with standard.	Devices pass criteria of 60601-1-4	**PASS** Devices are compliant with 60601-1-4
AAMI EC-11 Diagnostic electrocardiographic devices	Test the device per to ensure that the device meets the AAMI standard requirements for Diagnostic electrocardiographic devices	Units delivered to independently certified test lab for testing per compliance with standard.	Devices pass criteria of AAMI EC-11	**PASS** Devices are compliant with AAMI EC-11

60601-2-25 Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs	Test the device per to ensure that the device meets the 60601-2-25 requirements for the basic safety and essential performance of electrocardiographs	Units delivered to independently certified test lab for testing per compliance with standard.	Devices pass criteria of 60601-2-25	**PASS** Devices are compliant with 60601-2-25
60601-2-51 Particular Requirements For Safety, Including Essential Performance, Of Recording And Analysing Single Channel And Multichannel Electrocardiographs	Test the device per to ensure that the device meets 60601-2-51 the requirements for Safety, Including Essential Performance, Of Recording And Analysing Single Channel And Multichannel Electrocardiographs	Units delivered to independently certified test lab for testing per compliance with standard.	Devices pass criteria of 60601-2-51	**PASS** Devices are compliant with 60601-2-51
14971 Medical Devices – Application of Risk Management to Medical Devices	Test the device per to ensure that the device meet the requirements for the Application of Risk Management to Medical Devices	Risk management review performed according to Welch Allyn procedures	Devices pass criteria of 14971	**PASS** Risk Analysis Summary
60051724 --- Welch Allyn mobile stand - Large Platform Cart (LPC) Safety test	To verify the LPC meet the safety requirements per 60601-1	The subject device is verifies to be assembled with the cart as per assembly instructions and the LPC is verified to meet the safety requirements per 60601-1 by third party	The device can be installed as per assembly instruction and the LPC pass criteria of 60601-1	**PASS** the LPC is compliant with 60601-1 standard and can be used with the subject device

Clinical Performance Data:

No clinical studies were utilized for the purpose of obtaining safety and effectiveness data.

Device Comparison Table:

The Welch Allyn CP150™ Electrocardiograph is substantially equivalent in operation and performance to the Welch Allyn CP100™ and CP200™ Electrocardiographs (K072449).

Subject Device and Predicate Device Comparison

Characteristic	Subject Device	Predicate Devices	Differences
Device	CP150™ Electrocardiograph	CP100™ and CP200™ Electrocardiographs	Model number
Manufacturer	Welch Allyn, Inc.	Welch Allyn, Inc.	Same
510(k) Number	N/A	K072449	N/A
Product Code	DPS	DPS	Same
Classification Name	Electrocardiograph, Class II	Electrocardiograph, Class II	Same
Regulation Number:	21 CFR 870.2340	21 CFR 870.2340	Same
Intended Use	The Welch Allyn CP150™ Electrocardiograph is intended for use by trained operators in health facilities. The electrocardiograph provides the following diagnostic functions: • Acquiring, viewing, storing and printing ECG waveforms using ECG Front-End modules (patient cables) and associated accessories that provide signal acquisition for up to twelve (12) leads of patient ECG waveforms through surface electrodes adhered to the body. • Using optional algorithms to generate measurements, data presentations, graphical presentations, and	The Welch Allyn electrocardiographs are intended for use by trained operators in health facilities. The electrocardiograph will provide the following diagnostic functions: • Acquiring, viewing, storing, and printing ECG waveforms using ECG Front End modules and associated accessories that provide signal acquisition for up to twelve (12) leads of patient ECG waveforms through surface electrodes adhered to the body. • Using optional algorithms to generate measurements, data presentations, graphical presentations and	Same

Subject Device and Predicate Device Comparison			
Characteristic	**Subject Device**	**Predicate Devices**	**Differences**
	interpretative statements on an advisory basis. These are presented for review and interpretation by the clinician based upon knowledge of the patient, the result of physical examination, the ECG tracings, and other clinical findings.	interpretive statements on an advisory basis. These are presented for review and interpretation by the clinician based upon knowledge of the patient, the result of physical examination, the ECG tracings, and other clinical findings.	
Indications for Use	The electrocardiograph is one of the tools that clinicians use to evaluate, diagnose, and monitor patient cardiac function. The 12-lead interpretive algorithm provides a computer-generated analysis of potential patient cardiac abnormalities, which must be confirmed by a physician with other relevant clinical information.	The electrocardiograph is one of the tools that clinicians use to evaluate, diagnose, and monitor patient cardiac function. The 12-lead interpretive algorithm provides a computer-generated analysis of potential patient cardiac abnormalities, which must be confirmed by a physician with other relevant clinical information.	Same
Target Population	Adult and pediatric patients	Adult and pediatric patients	Same
Where Used	Health care facilities	Health care facilities	Same
ECG Storage	100 Adults ECG	50 Adults ECG	Upgrading to higher storage capacity
Printer	Thermal printer (internal)	Thermal printer (internal)	Same
Display type	LCD color touch screen	Color LCD	Upgrading to color touch screen
Alphanumeric keyboard	QWERTY keyboard - On screen	Physical QWERTY keyboard	Same function
Sterility	Device not supplied sterile	Device not supplied sterile	Same
Power	The electrocardiograph can run on AC or battery power	The electrocardiograph can run on AC or battery power	Same

Subject Device and Predicate Device Comparison			
Characteristic	**Subject Device**	**Predicate Devices**	**Differences**
Battery Operation	Yes 12 hours of continuous use or continuous printing of 250 ECG pages. The continuous test is based on performing 25 ECG's in a period of 12 hours Battery recharge – 6 hours to full capacity	Yes 4 hours of continuous use or continuous printing of 100ECG pages. The continuous test is based on performing 5 ECG's in a period of 4 hours Battery recharge – 12 hours to full capacity	Same Upgrading the battery capacity
Standard Compliance	EC 11 (AAMI/ANSI) IEC 60601-1 IEC 60601-1-2 IEC 60601-1-4 IEC 60601-2-25 IEC 60601-2-51 EN/ISO 14971	EC 11 (AAMI/ANSI) IEC 60601-1 IEC 60601-1-1 IEC 60601-1-2 IEC 60601-1-4 IEC 60601-2-25 IEC 60601-2-51	Same – except IEC 60601-1-1 does not apply to the CP150. The CP150 (like the CP100) does not have spirometry like the CP200. It no longer meets the definition of Medical System in IEC 60601-1-1
Filters	– 0.5 Hz high-performance base line filter – 35 Hz muscle-tremor filter – AC interference filter	– 0.5 Hz high-performance base line filter – 35 Hz muscle-tremor filter – AC interference filter	Same
ECG acquisition	ECG signal acquisition of up to 12 leads	ECG signal acquisition of up to 12 leads	Same
ECG Interpretation	Optional algorithm for adult (MEANS) and pediatric (PEDMEANS) patients	Optional algorithm for adult (MEANS) and pediatric (PEDMEANS) patients	For the PEDMEANS analysis – QT interval corrected for heart rate according to Hodges' formula: $QTc = QT + 1.75 \times (HR-60)$ was added as a user selectable option. This same analysis software is also used in Welch

Subject Device and Predicate Device Comparison			
Characteristic	**Subject Device**	**Predicate Devices**	**Differences**
			Allyn's Cardioperfect Workstation, and this modification to the PEDMEANS was covered in the submission K082478 for the Cardioperfect Workstation.
Weight	9.9 lb	11.6 lb	Slightly lighter
Dimensions	15x14.1x5.4 in.	16.2x15.6x6.2 in.	Slightly smaller
Connectivity	– 1 USB client, – 4 USB host ports, – 1 Ethernet port.	– 1 USB client – 1 SD slot – Wireless network	- Add 4 USB host ports - Remove the SD slot - Add 1 Ethernet port to replace wireless network
Accessories	– Patient Electrodes – Printer Paper – Patient Lead Cables DB15 connector to CP150	– Patient Electrodes – Printer Paper – Patient Lead Cables DB9 connector to CP100/CP200	All accessories are the same with the exception of a minor change to the connector type on the Unit connection end of patient lead cables

Conclusion

Based on the information presented in this 510(k) premarket notification the Welch Allyn CP150™ Electrocardiograph is considered substantially equivalent (as safe, as effective and performs as well as) the currently marketed devices (K072449) citied in this submission. The differences noted between the CP150 and the predicate devices do not impact safety or effectiveness based on the successfully conducted testing of the modified device.

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

July 3, 2013

Welch Allyn, Inc.
C/O Kevin Crossen
4341 State St. Rd.
P.o. Box 220
Skaneateles Falls, NY 13153-0220 US

Re: K131573
Trade/Device Name: Cp150 electrocardiograph
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: May 30, 2013
Received: June 3, 2013

Dear Kevin Crossen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K

Device Name: Welch Allyn CP150™ Electrocardiograph

Indications for Use:

The electrocardiograph is one of the tools that clinicians use to evaluate, diagnose, and monitor patient cardiac function.

The 12-lead optional interpretation algorithm provides a computer-generated analysis of potential patient cardiac abnormalities, which must be confirmed by a physician with other relevant clinical information.

Prescription Use ___x___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)